

JUN 05 2013

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k123518

### Company / Contact Person

Karen Lee  
Regulatory Affairs Specialist  
Thermo Fisher Scientific, Clinical Diagnostics Division  
46360 Fremont Blvd.  
Fremont, CA 94538  
Phone: (510) 979-5000 x31814  
Fax: (510) 979-5422  
E-mail: karen.lee@thermofisher.com

### Date Prepared

November 9, 2012

### Regulatory Declarations

Common / Usual Name	Carbamazepine Assay
Trade / Proprietary Name	Abbott Carbamazepine Assay
Classification Regulation	21 CFR 862.3645
Device Class	Class II
Device Regulation Panel	Toxicology
Product Code	KLT

### Indications For Use

The Carbamazepine assay is used for the in vitro quantitative measurement of carbamazepine in human serum or plasma on the ARCHITECT cSystems. The measurements obtained are used in monitoring levels of carbamazepine to help ensure appropriate therapy.

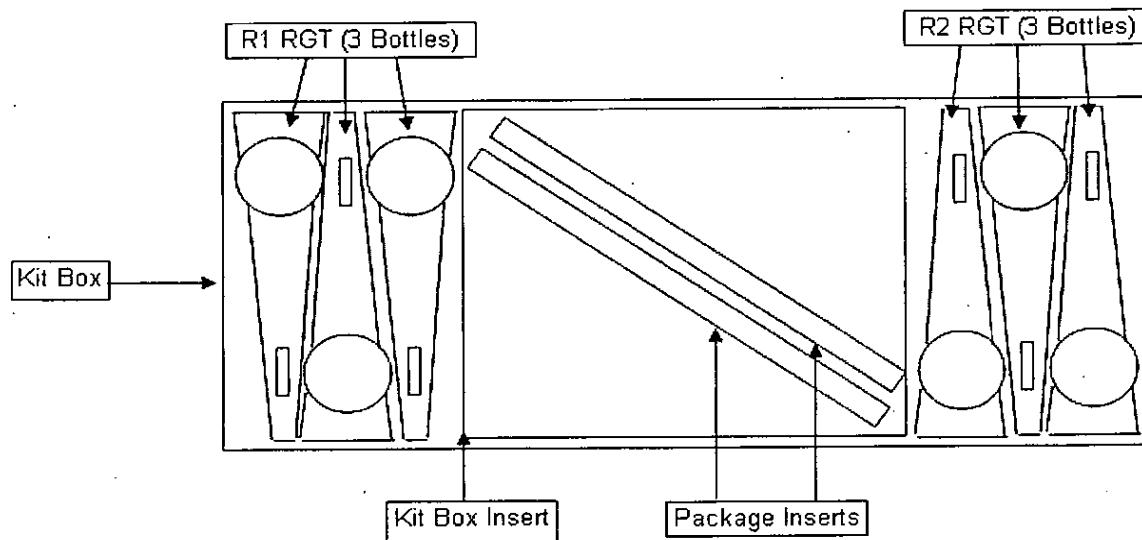
### Legally Marketed Device to Which Equivalency is Claimed

The Carbamazepine Assay is substantially equivalent to the previously cleared Abbott AeroSet® Carbamazepine Assay (k993028).

### Device Description

The Carbamazepine Assay kit is supplied ready-to-use in liquid form, for storage at 2 to 8°C. Each Carbamazepine Assay kit is packaged in a rectangular cardboard box divided into three sections. One section will contain three bottles of Antibody Reagent (R1), one section will contain three bottles of Microparticle Reagent (R2), and the last section will contain the package insert. Each kit is sufficient for 300 tests. The configuration is as follows:

Component	Description	Configuration
R1 Antibody Reagent	<1.0% Anti-Carbamazepine monoclonal antibody (mouse) in Bis-Tris buffer and <0.09% sodium azide as preservative.	3 x 27 mL
R2 Microparticle Reagent	<1.0% Carbamazepine-coated microparticles in Tris buffer containing <0.09% sodium azide as preservative.	3 x 9 mL



### Comparison of Technological Characteristics

Comparison	Proposed Device	Predicate
<b>Proprietary Name</b>	Abbott Carbamazepine Assay	Abbott AeroSet® Carbamazepine Assay (k993028)
<b>Intended Use</b>	The Carbamazepine assay is used for the in vitro quantitative measurement of carbamazepine in human serum or plasma on the ARCHITECT cSystems.	The assay is intended for use in the quantitative analysis of Carbamazepine in human serum or plasma.
<b>Test Principle</b>	The Carbamazepine assay is a homogeneous particle-enhanced turbidimetric inhibition immunoassay (PETINIA) used for the analysis of carbamazepine in serum or plasma. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the carbamazepine antibody reagent. The carbamazepine-coated microparticle reagent is rapidly agglutinated in the presence of the anti-carbamazepine antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance change is measured photometrically, and is directly proportional to the rate of agglutination of the particles. When a sample containing carbamazepine is added, the agglutination reaction is partially inhibited, slowing down the rate of absorbance change. A concentration-dependent classic agglutination inhibition curve can be obtained, with maximum rate of agglutination at the lowest carbamazepine concentration and the lowest agglutination rate at the highest carbamazepine concentration.	The Carbamazepine assay is a homogeneous enzyme immunoassay technique used for the analysis of carbamazepine in biological fluids. The assay is based on competition for antibody binding sites between the analyte drug in the specimen and exogenous drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH). Since G6PDH activity decreases upon binding to the antibody, the concentration of drug in the specimen can be measured in terms of enzyme activity. Active G6PDH reduces nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme NAD functions only with the bacterial ( <i>Leuconostoc mesenteroides</i> ) enzyme employed in the assay.
<b>Sample Matrix</b>	Human Serum or Human Plasma	Human Serum or Human Plasma
<b>Reagent</b>	Liquid Ready-to-Use (Antibody reagent, Carbamazepine-coated microparticle reagent)	Liquid Ready-to-Use (Antibody reagent, Carbamazepine-labeled enzyme reagent)
<b>Storage</b>	2-8°C	2-8°C
<b>Calibrator</b>	Liquid Ready-to-Use, six levels (0.0, 2.0, 4.0, 8.0, 12.0, and 20.0 µg/mL)	Liquid Ready-to-Use, six levels (0.0, 2.0, 4.0, 8.0, 12.0, and 20.0 µg/mL)
<b>Assay Range</b>	1.9 to 20.0 µg/mL	0.5 to 20.0 µg/mL

## **Summary of Performance Testing**

### **Functional Sensitivity (LOQ)**

Limit of Quantitation (LOQ) determines the lowest concentration which results a CV of inter assay precision at 7% that has been measured over an extended period. The results demonstrate that the LOQ is 1.9 µg/mL and meet design acceptance criteria.

### **Precision**

Carbamazepine samples tested for precision following a CLSI protocol. In the study, the total run %CV was less than or equal to 6.3% and meets design acceptance criteria.

### **Spike Recovery**

Negative serum samples were spiked with carbamazepine at concentrations across the assay range. All of the samples recover within ±10% or ±0.4 µg/mL error of the HPLC results.

### **Method Comparison**

Samples were tested in the Carbamazepine Assay and compared to HPLC and AeroSet Carbamazepine Assay (k993028). The assay correlated well with HPLC as follows:  $y = 1.093x + 0.372$ ,  $R = 0.9584$ ,  $n=105$ . The assay also correlated well with the AeroSet Carbamazepine Assay as follows:  $y = 0.905x + 0.564$ ,  $R = 0.9675$ ,  $n = 103$ .

### **Matrix Comparison**

The following matrices were tested and may be suitable for use in the Carbamazepine Assay: serum in glass, serum in plastic, serum separator tube (SST) in plastic, plasma with sodium fluoride/potassium oxalate in plastic, plasma with sodium heparin in plastic and glass, plasma with lithium heparin in plastic with or without gel, plasma with K3 EDTA in glass and plastic, plasma with K2 EDTA in plastic, and sodium citrate in plastic and glass.

### **Specificity**

The assay showed minimal to no cross reactivity to other medications potentially administered with carbamazepine. The assay also showed minimal to no interference to endogenous substances up to the concentrations tested.

### **Linearity**

Samples were tested to demonstrate linearity throughout the assay range. Results demonstrate that the assay performs in a linear fashion from 0.5 to 20 µg/mL.

### **Onboard Stability**

Using the Abbott Architect cSystem, the reagents were stable onboard for up to 45 days.

### **Standard Curve Calibration Stability**

Using the Abbott Architect cSystem, the standard curve calibration was stable for up to 7 days.

### **Reagent Shelf Life Stability**

Studies showed that the reagents will be stable at 2-8°C for 24 months.

**Conclusion**

Substantial equivalence of the Abbott Carbamazepine Assay to the previously cleared Abbott AeroSet® Carbamazepine Assay (k993028) has been demonstrated through performance testing (Section 18) to verify that the device functions as intended and design specifications have been satisfied.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

June 5, 2013

Microgenics Corporation  
C/O Ms. Karen Lee  
46360 Fremont Blvd.  
FREMONT CA 94538

**Re: K123518**

Trade/Device Name: Abbott Carbamazepine Assay  
Regulation Number: 21 CFR 862.3645  
Regulation Name: Neuroleptic drugs radioreceptor assay test system  
Regulatory Class: II  
Product Code: KLT  
Dated: April 26, 2013  
Received: April 30, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties.—We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Carol C. Benson -S for**

Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## **Indications for Use Statement**

**510(k) Number (if known)**

k123518

**Device Name**

Abbott Carbamazepine Assay

**Indications For Use**

The Abbott Carbamazepine assay is used for the in vitro quantitative measurement of carbamazepine in human serum or plasma on the ARCHITECT cSystems. The measurements obtained are used in monitoring levels of carbamazepine to help ensure appropriate therapy.

Prescription Use X

AND/OR

Over-The-Counter Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

---

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF  
NEEDED)

---

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S  
2013.06.04 09:54:12 -04'00'

---

Division Sign-Off  
Office of In Vitro Diagnostics and Radiological Health

---

510(k) k123518